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10/045,028	01/15/2002	Tsukasa Matsumoto	2489.111	9164

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/09/2003.

Please find below and/or attached an Office communication concerning this application or proceeding.

0013

Office Action Summary

Application No.

10/045,028

Applicant(s)

MATSUMOTO, TSUKASA

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/520,624.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/520,624, filed on March 7, 2000. 2. The disclosure is objected to because of the following informalities: In the brief description of the drawings provided in the response dated October 6, 2003, there is no description of figure 5h.

Appropriate correction is required.

3. Claims 2 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In parts a), b), c), d) and e) of claim 2, the phrase "said blood liquid" should be changed to -said blood—since the blood liquid is recited in claim 1 as being formed as a result of the fracturing of the leukocyte cell membranes. Therefore, the blood liquid cannot be subjected to one of the physical means for fracturing cell membranes in claim 2 since it does not exist until after the fracturing. See this same problem in claim 8.

At the end of line 14 in claim 7, the word -and—should be inserted. On line 16 of claim 7, the phrase "said pre-selected diseases" lacks antecedent basis and should be changed to -said pre-determined diseases—so as to use the same terminology used earlier in the claim.

Claim 12 is indefinite since it depends on itself. Claim 12 should depend from claim 11.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. (submitted in the Information Disclosure Statement filed on April 8, 2002).

In reference example 5 in columns 24-25 of Hashimoto et al (see lines 63-67 in column 24 and lines 1-10 in column 25), a method is taught for obtaining leucocyte components from human blood which comprises fracturing the cell membranes of the leucocytes by vigorously agitating the leucocytes in a vortex mixer to effect cell rupture. This step constitutes a physical means of fracturing the cell membranes of the leucocytes. As a result of the cell rupture, the nucleic acids in the leucocytes are released. The nucleic acids are then subject to electrophoresis on an agarose gel in order to separate these leucocyte components from one another.

6. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gottlieb (submitted in the Information Disclosure Statement filed on April 8, 2002).

Gottlieb teaches of a method for obtaining leucocyte components from human blood which comprises a first step of lysing the cell membranes of the leucocytes by subjecting the leucocytes to several cycles of freeze-thawing, and a second step of separating the released leucocyte components from one another by either dialysis or a procedure which involves centrifugation followed by ultrafiltration. See examples 2 and 3 in columns 7-8 of Gottlieb (lines 65-68 in column 7 and lines 1-45 in column 8). The cycles of freeze-thawing constitute a physical means of fracturing the cell membrane of the leucocytes, and the centrifugation/ultrafiltration constitutes a means of separating and collecting the individual leucocyte components.

7. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Wissler et al.

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Wissler et al teach of a method for isolating a component known as angiotropins from cultured leukocytes. In the method, leukocytes are collected and cultured under sterile conditions. During culturing, the angiotropins migrate out of the cells and into the culture medium. The culture is terminated by separating the cells from the culture medium by centrifugation. The culture supernatant is further centrifuged to remove suspended particles. The resultant clear supernatant is found to contain the angiotropins. See Example A, part A.1. in columns 19 and 20 of Wissler et al. In an alternative embodiment, the cultured leukocytes are first physically homogenized, which inherently causes at least some of the leukocytes to lyse. After the homogenization, the leukocytes are centrifuged to separate the angiotropins from the blood liquid resulting from the homogenization in order to collect the separated angiotropins. See Example D in column 25 of Wissler et al. Therefore, Wissler et al teach of using a physical means for fracturing the cell membrane of at least some leukocytes in a sample (i.e. homogenization) in order to release leukocyte components therein, followed by a step of separating the leukocyte components from the blood liquid by centrifugation.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb.

For a teaching of Gottlieb, see previous paragraphs in this Office action.

Gottlieb fails to teach of the specific conditions under which the cycles of freeze-thawing take place. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to determine the optimum temperatures/conditions for freezing and thawing the leucocytes in the method of Gottlieb since temperature is a result effective variable that can be varied as desired by a person performing the method in order to achieve optimum cell lysis.

Gottlieb also fail to teach of lysing leukocytes from healthy persons in the method. However, it would have been obvious to one of ordinary skill in the art to use leukocytes from healthy individuals in the method taught by Gottlieb so as to obtain leukocyte components that are substantially normal and that can be used in medical procedures without any adverse affects.

11. Claim 6 is allowable over the prior art of record since none of the prior art of record teaches or fairly suggests the use of isolated leukocyte components obtained from cultured leukocyte fractionation to determine and produce therapies for a variety of different diseases.

12. Claim 7 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action since none of the prior art of record teaches or fairly suggests a method for identifying therapeutically effective leukocyte components by isolating leukocyte components from healthy human cells, selectively combining

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the components with blood cells obtained from humans having known diseases, and observing the effects of the leukocyte components on erythrocyte cells.

13. Claims 8-13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.

14. Applicant's arguments filed October 6, 2003 have been fully considered but they are not persuasive.

The declaration filed on October 6, 2003 is acceptable. The previous objections to the abstract and disclosure in the last Office action dated June 4, 2003 are withdrawn in view of Applicant's amendments to these sections of the application. However, a brief description of Figure 5h should be provided in the specification. The previous rejections of the claims under 35 USC 112, second paragraph are also withdrawn in view of Applicant's amendments to the claims. However, some new rejections of the claims under this statute are set forth above as necessitated by Applicant's amendments.

Applicant argues the rejections of the claims under 35 USC 102 and 35 USC 103 as anticipated by or obvious over the references to Hashimoto et al, Gottlieb and Wissler et al by stating that no single reference teaches or suggests a method for isolating substantially all or a plurality of the cellular components found in leukocytes as a result of the physical fractionation of the leukocytes. In response to this argument, it is noted that claims 1-5 do not recite isolating "all or a plurality of different leukocyte components" as argued by Applicant. These claims merely recite isolating "leukocyte components", which can be interpreted as any single component found in a leukocyte in multiple copies (i.e. multiple copies of DNA, multiple copies

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of the same type of protein found in leukocytes, etc.). The specification only provides support for the isolation of "leukocyte components" as recited in claims 1-5. There is no support in the specification for the isolation of all or a plurality of different types of leukocyte components (i.e. DNA, RNA, organelles, nucleus, proteins, etc.), as argued by Applicant. For these reasons, Applicant's arguments are not persuasive in regards to claims 1-5..

Claims 6-13 have been indicated as allowable in view of Applicant's persuasive arguments with regards to these claims. It is noted that this Office action is not being made final since claim 5 is newly rejected under 35 USC 103 as being obvious over Gottlieb.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached every Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3599.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

December 8, 2003

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1700